UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IRA BRIEF and CATHIE BRIEF, husband and wife, **Plaintiffs,** **v.** **IDELLE LABS, LTD. and JOHN DOE 1 through JOHN DOE 75 (fictitious),** **Defendants.**	Civ. No. 2:22-cv-05085 (WJM) **OPINION**

In this product liability action, Defendant Idelle Labs, Ltd. ("Idelle" or "Defendant") moves to dismiss Plaintiffs' Ira Brief and Cathie Brief ("Plaintiffs") Amended Complaint ("AC") for failure to state a claim upon which relief may be granted pursuant to Fed. R. Civ. P. 12(b)(6). ECF No. 20. The Court decides the matter without oral argument. Fed. R. Civ. P. 78(b). Upon careful review of the parties' submissions, for the reasons stated below, Defendant's motion to dismiss is **granted**.

I. BACKGROUND

Plaintiff Ira Brief ("Mr. Brief") was diagnosed with Acute Myeloid Leukemia ("AML") on February 16, 2022. AC, ¶ 41, ECF No. 16. A November 2021 report by Valisure ("Valisure Report"),[1] a third-party consumer protection organization, shows that benzene was detected at 2.00 ppm or higher in a variety of spray deodorant and antiperspirant products including Sure® antiperspirant identified by UPC number 883484002278 and three different Lot numbers. *See id.* at ¶ 19. Based on that Valisure Report, Plaintiffs claim that Mr. Brief's AML was caused by exposure to benzene from the Sure® aerosolized antiperspirant deodorant products ("Products") that he used "regularly for many years, beginning approximately in the 1980s." *Id.* at ¶¶ 35, 42. According to the CDC "Facts About Benzene" website cited in the AC, "[l]ong-term exposure to high levels of benzene in the air can cause leukemia." *Id.* at ¶¶ 4, 21.[2]

[1] https://assets-global.website-files.com/6215052733f8bb8fea016220/626af96f521a0584e70e50eb_Valisure%20FDA%20Citizen%20Petition%20on%20Body%20Spray%20v4.0%5B260%5D.pdf

[2] https://emergency.cdc.gov/agent/benzene/basics/facts.asp

The Sure® brand was created by Proctor & Gamble in or around 1972 and was acquired by Helen of Troy Limited ("Helen") in 2010. *Id.* at ¶¶ 2, 14. After the acquisition, Helen's wholly owned subsidiary, Idelle, distributed the Sure® products. *Id.* at ¶¶ 10, 15. The last time Mr. Brief purchased the Sure® antiperspirant was in or around March 2021. *Id.* at ¶ 35. This action, based on diversity jurisdiction, asserts product defect in violation of the New Jersey Products Liability Act, N.J.S.A. 2A:58C-1, *et seq.* ("PLA").[3] Defendant moves to dismiss the entire AC.

II. DISCUSSION

A. Fed. R. Civ. P. 12(b)(6) Standard

Federal Rule of Civil Procedure 12(b)(6) provides for the dismissal of a complaint, in whole or in part, if the plaintiff fails to state a claim upon which relief can be granted. The moving party bears the burden of showing that no claim has been stated. *Hedges v. United States,* 404 F.3d 744, 750 (3d Cir. 2005). Dismissal is appropriate only if, accepting all the facts alleged in the complaint as true, the plaintiff has failed to plead "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly,* 550 U.S. 544, 570 (2007); *see also Umland v. PLANCO Fin. Serv., Inc.,* 542 F.3d 59, 64 (3d Cir. 2008). This assumption of truth is inapplicable, however, to legal conclusions couched as factual allegations or to "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements." *Ashcroft v. Iqbal*, 556 U.S. 662 (2009). Although a complaint need not contain detailed factual allegations, "a plaintiff's obligation to provide the 'grounds' of his 'entitlement to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Twombly,* 550 U.S. at 555. Thus, the factual allegations must be sufficient to raise a plaintiff's right to relief above a speculative level, *see id.* at 570, such that the court may "draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678 (citing *Twombly,* 550 U.S. at 556). While "[t]he plausibility standard is not akin to a probability requirement' ... it asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.*

Before reaching the merits of the pending motion, the Court addresses two threshold issues. First, in ruling on a motion to dismiss, a court "may not consider matters extraneous to the pleadings." *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir.1997). Rather, a court is to rely on "only the allegations contained in the complaint, exhibits attached to the complaint and matters of public record." *Schmidt v. Skolas*, 770

[3] "A manufacturer or seller of a product shall be liable in a product liability action only if the claimant proves by a preponderance of the evidence that the product causing the harm was not reasonably fit, suitable or safe for its intended purpose because it: a. deviated from the design specifications, formulae, or performance standards of the manufacturer or from otherwise identical units manufactured to the same manufacturing specifications or formulae, or b. failed to contain adequate warnings or instructions, or c. was designed in a defective manner." N.J.S.A. § 2A:58C-2.

F.3d 241, 249 (3d Cir. 2014); *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d at 426 ("a document integral to or explicitly relied upon in the complaint may be considered...."). Thus, for purposes of the current motion, apart from matters of public record and materials relied on in the AC such as the Valisure Report and the CDC "Facts About Benzene" website, the Court will not consider Mr. Brief's Certification, photographs, or other exhibits extraneous to the AC that Plaintiffs have submitted in opposition to Defendant's motion to dismiss. *See* Cert. of Vincent Cheng, ECF No. 25-2.

Second, the Court rejects Plaintiffs' repeated assertion that it is premature to resolve any legal issues without the benefit of discovery. For example, Plaintiffs argue that without discovery, it is "unrealistic" to require them to allege a defect in manufacturing process that resulted in benzene contamination. Pls.' Opp'n Br., at 12. While at the pleading stage Plaintiffs need not set forth a manufacturing defect with precision, *see Vicente v. DePuy Synthes Cos.,* 570 F. Supp. 3d 232, 243 (D.N.J. 2021), to defeat a motion to dismiss, Plaintiffs must satisfy the PLA pleading requirements and state plausible claims for relief. A motion to dismiss, by express rule and design, must be made before a responsive pleading and hence before discovery. Fed. R. Civ. P. 12(b).

B. Elements of PLA

To plead a *prima facie* PLA case, a plaintiff must also show that: "(1) the product was defective; (2) the defect existed when the product left the hands of the defendant; (3) the defect proximately caused injuries to the plaintiff; and (4) the injured plaintiff was a reasonably foreseeable user." *Barrett v. Tri-Coast Pharmacy, Inc.*, 518 F. Supp. 3d 810, 825 (D.N.J. 2021) (citing *Myrlak v. Port Auth. of New York & New Jersey*, 157 N.J. 84, 97 (1999)). "A product is deemed defective when it is not reasonably fit, suitable, or safe for the ordinary or foreseeable purpose for which it is sold," because of a manufacturing defect, a design defect, or a failure to warn. *Barrett*, 518 F. Supp. 3d at 825 (citing *Myrlak*, 157 N.J. at 97). Here, Plaintiffs assert all three of these theories of liability under the PLA, each of which "imposes its own additional pleading requirements," *Hindermyer v. B. Braun Med. Inc.*, 419 F. Supp. 3d 809, 823 (D.N.J. 2019), discussed below.

To show that the Products Mr. Brief used were defective, Plaintiffs rely on the Valisure Report, which indicates that three samples of Sure® antiperspirant spray products from three specific lots contained varying amounts of benzene. *See* Valisure Report at 12-13; AC, ¶ 20. However, there was "significant variability" of benzene from batch to batch, even within a single brand" and out of 108 batches tested by Valisure, only "59 product batches had detectable levels of benzene." *Id.* at 8, 12-13; *see also Rooney v. Procter and Gamble Co.*, 2022 WL 17092124 at *3 (E.D. La. Nov. 21, 2022). Since not even all the samples tested by Valisure contained benzene, the Court will not infer that the Products used by Mr. Brief also contained benzene. *See Rooney*, 2022 WL 17092124, at * 3.

Next, Plaintiffs conclude that Mr. Brief used defective Products because he purchased and is "in possession" of Sure® antiperspirant products that have been recalled. AC, ¶ 35. However, the AC is devoid of any factual allegations regarding the recall and how it relates to Plaintiffs' claims. Instead, Mr. Brief submits a certification that the Product in his possession matches the UPC number and expiration date of the recalled products. *See* Certif. of Plaintiff Ira Brief, ¶ 4, ECF No. 25-4. As noted above, new factual allegations outside of the pleadings cannot be considered on a motion to dismiss.

Even if the Court could consider such extraneous allegations, the UPC number only references the general Secret product type rather than a specific batch, which is identified by lot number. Thus, any matching UPS numbers at most only confirms the type of Secret antiperspirant product in Plaintiff's possession. *See Rooney v. Procter and Gamble Co.*, 2023 WL 1419870, at *4 (E.D. La. Jan. 31, 2023). Nevertheless, Plaintiffs insist that they need not identify any specific lot numbers to allege that Mr. Brief used the recalled products because in a class action[4] pending in the Southern District of New York involving the same Sure® deodorant products, claimants were not required to identify specific lot numbers to submit settlement claim forms. However, without a doubt, the requirement of a settlement claim form in an action pending in another court, even had it been pled in the AC, has no bearing on Plaintiffs' burden to properly plead claims under the PLA.

In any event, the existence of a voluntary recall does not prove a defect. *See Goldin v. Smith & Nephew, Inc.*, 2013 WL 1759575, at *4 (S.D.N.Y. Apr. 24, 2013); *see e.g., Rooney,* 2023 WL 1419870 (finding that plaintiff failed to allege that Secret antiperspirant that she used exposed her to benzene despite defendant's voluntary recall). Moreover, the Court will not consider a recall as an admission of a defect particularly where it is part of a putative class action settlement. *See e.g., Giles v. Phelan, Hallinan & Schmieg, L.L.P.*, 901 F. Supp. 2d 509, 533 (D.N.J. 2012).

Finally, Plaintiffs have also insufficiently pled causation. Plaintiffs claim that Mr. Brief used the Products "regularly" for "many years," *see* AC at ¶ 35, but have not alleged facts to show that Mr. Brief's exposure was to "high levels" of benzene, which is what can cause leukemia according to the CDC's "Facts About Benzene" cited in the AC. *See id.* at ¶ 21.

i. Manufacturing Defect

In addition to the general shared standard discussed above, to plead a manufacturing defect under the PLA, Plaintiffs must also allege that the Products "deviated from the design specification, formulae, or performance standards of the manufacturer or from otherwise identical units manufactured to the same manufacturing specifications or formulae." N.J.S.A. § 2A:58C-2(a). That is, a manufacturing defect exists if a "particular

[4] *Delcid v. TCP HOT Acquisition LLC & Idelle Labs, Ltd.*, No. 21-09569 (S.D.N.Y.)

product used by the plaintiff fails to conform to those standard or other units of the same kind." *Barrett*, 518 F. Supp. 3d 810, 827 (D.N.J. 2021) (internal quotes and cites omitted).

The AC does not identify any defect in the manufacturing process (design specification, formulae, or performance) that may have caused benzene contamination in those Products. Boilerplate conclusory allegations that the Products "deviated from the design specifications, formulae, and/or performance standards by the presence of benzene," AC, ¶49(k), are insufficient to meet minimum pleading standards. *See Twombly*, 550 U.S. at 570; *see, e.g., Hindermyer*, 419 F. Supp. 3d at 827 (dismissing manufacturing defect claim for pleading deficiencies because "Plaintiff has not identified, even in general terms, a particular error or mishap in the manufacturing process that caused [the product] to deviate from Defendants' own standards, nor does she contend that her device failed to conform to other identical units."); *Dingler v. Am. Med. Sys., Inc.*, No. 19-8672, 2019 WL 6310057, at *2 (D.N.J. Nov. 25, 2019) (dismissing manufacturing defect claim that products caused adverse reactions and did not perform their intended purposes because plaintiff did not allege any standard from which products deviated). Plaintiffs' suggestion that there was no benzene detected in other "similar" deodorant manufacturers' products in the Valisure Report is immaterial to a manufacturing defect claim, which requires that the Sure® Products deviated from otherwise "*identical* units manufactured to the *same* manufacturing specifications or formulae." N.J.S.A. § 2A:58C-2(a).

Finally, at its core, Plaintiffs' lawsuit alleges that Mr. Brief's exposure to benzene from "regular" use of the Sure® Products for "many years" caused his AML. AC, ¶¶ 35, 42. That assertion presumes that the Products used by Mr. Brief were "regularly" contaminated with benzene, which is inconsistent with a manufacturing defect claim that those Products deviated in design, formulae, or performance from "otherwise identical units manufactured to the same manufacturing specifications or formulae." In other words, "common sense dictates that a product cannot deviate from another identical product" when Plaintiffs claim is that over the "many years" of "regular" use, the Products "suffer[ed] from the same inherent flaw." *See Hindermyer*, 419 F. Supp. 3d at 826. Accordingly, the manufacturing defect claim is **dismissed with prejudice.**

ii. Design Defect

"To establish a prima facie case of design defect, the plaintiff must assert that the product could have been designed more safely and present, under a risk-utility analysis, the existence of an alternative design that is both practical and feasible." *Barrett*, 518 F. Supp. 3d at 826 (citing *Mendez v. Shah*, 28 F. Supp. 3d 282, 297 (D.N.J. 2014)). While no *per se* rule requires that a plaintiff "'must, under all circumstances, provide a reasonable alternative design,' a plaintiff must plead either that the product's risk outweighs its harm, or that an alternative design exists, in order to state a claim for a design defect under the PLA." *Id.* (citing *Smith v. Keller Ladder Co.*, 275 N.J. Super. 280, 284 (App. Div. 1994)).

Plaintiffs claim that the Sure® antiperspirant could have been "designed more safely by not utilizing the propellant that exposed Plaintiff to benzene." AC, ¶ 49(i). Plaintiffs further assert that because the Valisure Report shows that other deodorants manufactured by other companies did not contain the same benzene levels as Sure® Products, that evidences the availability of other technologically feasible and practical alternative designs that would have reduced or prevented Mr. Brief's injury. *Id.* at ¶ 5. While Plaintiffs allege the existence of an alternative design, Plaintiffs have not sufficiently pled that the Products Mr. Brief used were defective. *See* discussion above. The design defect claim is **dismissed without prejudice**.

iii. Failure to Warn

In a failure to warn case, "the duty to warn is premised on the notion that a product is defective absent an adequate warning for foreseeable users that the product can potentially cause injury." *Barrett*, 518 F. Supp. 3d at 826–27 (citing *Clark v. Safety–Kleen Corp.*, 179 N.J. 318, 336, 845 A.2d 587 (2004)). The plaintiff must establish that the defendant had a duty to warn, that an adequate warning was not provided, and that the absence of a warning proximately caused the injury. *Id.* at 827 (citing *James v. Bessemer Processing Co.*, 155 N.J. 279, 714 A.2d 898, 907 (1998)). An adequate warning is defined by statute as "one that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and that communicates adequate information on the dangers and safe use of the product." N.J.S.A. 2A:58C-4. If the product contains an adequate warning or instruction, the manufacturer is not liable for harm caused by a failure to warn. *Id.* Where warnings "in connection with a drug" are approved by the FDA, there is a rebuttable presumption that those warnings are adequate. N.J.S.A. 2A:58C-4.

Sure® antiperspirant spray products are regulated as drugs. AC, ¶ 18. Thus, to rebut the presumption, Plaintiffs must present "clear and convincing evidence that a manufacturer knew or should have known, based on newly acquired information, of a causal association between the use of the drug and "a clinically significant hazard" and that the manufacturer failed to update the label accordingly." *In re Accutane Litig.*, 235 N.J. 229, 275, 194 A.3d 503, 530 (2018). "'For all practical purposes, absent deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects, compliance with FDA standards should be virtually dispositive of such claims.'" *Vicente v. Johnson & Johnson*, No. 20-1584, 2020 WL 7586907, at *13 (D.N.J. Dec. 21, 2020) (citing *Perez v. Wyeth Labs., Inc.*, 161 N.J. 1, 25 (1999), amended, No. 20-1584, 2021 WL 2328159 (D.N.J. June 7, 2021)).

Plaintiffs insist they can overcome the PLA's rebuttable presumption that the warning is adequate once discovery is conducted. However, the AC does not contain any facts to support an inference that Defendant knew or should have known, based on newly acquired information, of any link between use of its Sure® Products and leukemia.

Although a plaintiff is not expected to possess full evidence to support their claims prior to discovery, here, Plaintiffs have not pled *any* facts to demonstrate that "deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects" rendered any FDA compliant warnings inadequate. The claim for failure to warn defect is **dismissed without prejudice.**

C. Punitive Damages[5]

Defendant argues that Plaintiffs are not entitled to any punitive damages under the PLA. As Plaintiffs have failed to state a claim for violations of the PLA, the claim for punitive damages is also **dismissed without prejudice.** *See e.g., Hindermyer*, 419 F. Supp. 3d at 831.

III. CONCLUSION

For the reasons noted above, Defendant's Fed. R. Civ. P. 12(b)(6) motion to dismiss is **granted**. The Amended Complaint is **dismissed without prejudice** except for the manufacturing defect claim which is **dismissed with prejudice**. Plaintiffs may file an amended pleading curing the deficiencies noted herein within 30 days of the date of this Opinion.

WILLIAM J. MARTINI, U.S.D.J.

Date: April 10, 2023

[5] Although the AC seeks costs of suit, Defendant believes Plaintiffs do not intend to dispute that that remedy is unavailable under the PLA. Def. Br., at n. 7. Plaintiffs do not contest or even address this issue in their opposition.